

FEB 25 2002

K014201

**510(k) SAFETY AND EFFECTIVENESS SUMMARY**

Trade Name: Aaron Reusable Electrosurgical Electrode  
Common Name: Electrosurgical Electrode  
Classification Name: Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400)

**Aaron Reusable Electrosurgical Electrodes** are non-sterile, reusable electrosurgical electrodes are used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels during surgery.

The **Aaron Reusable Electrosurgical** is substantially equivalent to **Aaron Electrosurgical Electrodes** (K931338 and K942986) in operation, intended use, energy source, and method of preparation. Performance claims for the reusable electrodes differ from the predicate device in that they are not sold sterile and that they may be cleaned and resterilized by steam under pressure. **Aaron Reusable Electrosurgical Electrodes** in the loop configuration may be cleaned and sterilized up to 5 times. **Aaron Reusable Electrosurgical Electrodes** in the blade, needle, and ball configurations may be cleaned and sterilized up to 25 times. Cleaning and resterilization processes are validated in accordance with Good Hospital Practice: Steam Sterilization and Sterility Assurance (ANSI/AAMI ST46: 1993) and Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities: A Guide for Device Manufacturers (AAMI TIR 12: 1994). The validated cleaning and sterilization processes are provided in device labeling and instructions.

Testing performed on **Aaron Reusable Electrosurgical Electrodes** indicate that the devices are substantially equivalent in method of operation, safety, and performance.

In conclusion, **Aaron Reusable Electrosurgical Electrodes** substantially equivalent to predicate devices (Aaron Electrosurgical Electrodes) in methods of operation, intended use, and results derived from operation.

Submitted By: Richard Kozloff  
Vice-President ; Quality Assurance  
Aaron Medical Industries  
7100 30<sup>th</sup> Avenue North  
St. Petersburg, FL 33710

Contact Person: Richard Kozloff  
Date: December 17, 2001



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**FEB 25 2002**

Mr. Richard Kozloff  
Vice President, Quality Assurance  
and Regulatory Affairs  
Aaron Industries  
7100 30<sup>th</sup> Avenue North  
St. Petersburg, Florida 33710

Re: K014201  
Trade/Device Name: Aaron Reusable Electrosurgical Electrodes  
Regulation Number: 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: December 20, 2001  
Received: December 21, 2001

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

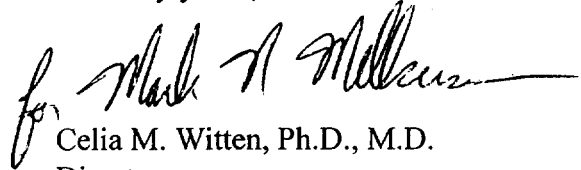
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**AARON MEDICAL INDUSTRIES  
AARON REUSABLE ELECTROSURGICAL ELECTRODE**

**510 (K) NOTIFICATION**

**INDICATIONS FOR USE**

510(k) Number (if known): K014201

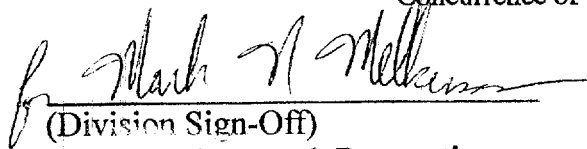
**Device Name:** Aaron Reusable Electrosurgical Electrodes

**Indications for Use:**

**Aaron Reusable Electrosurgical Electrodes** are non-sterile, reusable electrosurgical electrodes, used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K014201